

JUN 30 2008

## SPECIAL 510(K) SUMMARY

**Creaspine SupStance Vertebral Body Replacement System,  
Line Extension**

Proprietary Name: Creaspine SupStance Vertebral Body Replacement System

Common Name: Spinal Vertebral Body Replacement System

Proposed Regulatory Class: Class II  
Spinal intervertebral body fixation orthosis  
21 CFR 888.3060

Device Product Code: 87 MQP, Spinal Vertebral Body Replacement Device

For Information Contact: Marc Bernard  
Regulatory Affairs Director

PTIB Xavier Arnozan  
Avenue du Haut-Lévêque  
33600 Pessac – France  
Telephone +33 557 102 854  
Fax: +33 557 102 886  
Email: [marc.bernard@creaspine.com](mailto:marc.bernard@creaspine.com)

Date Summary Prepared: June 3, 2008

**Predicate Devices**

The proposed Creaspine SupStance Vertebral Body Replacement System (SupStance VBR System), Line Extension is substantially equivalent to the Creaspine SupStance VBR System subject of K072537 and the following legally marketed spinal vertebral body replacement devices:

- Surgical Titanium Mesh™ System (DePuy-Acromed™, Inc., K003043)
- Surgical Dynamics Mesh Cage System (United States Surgical, K003709)

**Device Description**

The proposed Creaspine SupStance VBR System, Line Extension, is a modification of the original Creaspine SupStance VBR System that was the subject of K072537. This device modification has been submitted as a Special 510(k) Premarket Notification because the proposed SupStance VBR System, Line Extension, is identical in intended use and fundamental scientific technology to the parent SupStance VBR System originally described in K072537.

The modifications made to the parent device to produce the proposed SupStance VBR System, Line Extension, are limited to the expansion of the implant (cage) dimensions available. The line extension includes the implants with the length and diameter combinations bolded in the following table:

<b>Diameter</b>	Ø19		Ø22	Ø25	Ø28
<b>Angulation</b>	0°	5°	5°	5°	5°
<b>Length</b>	30	30	30	30	30
	32.5	32.5	32.5	32.5	32.5
	35	35	35	35	35
	37.5	37.5	37.5	37.5	37.5
	40	40	40	40	40
	42.5	42.5	42.5	42.5	42.5
	45	45	45	45	45
	47.5	47.5	47.5	47.5	47.5
	50	50	50	50	50
				52.5	52.5
				55	55

#### **Intended Use**

The SupStance VBR System, Line Extension is a vertebral body replacement system intended to replace a vertebral body. The SupStance VBR System is designed for use in the thoraco-lumbar spine (T1- L5) to replace a collapsed, damaged, or unstable vertebral body during tumor or trauma (i.e., fracture) management procedures. The SupStance VBR System is intended to be used with supplemental internal fixation systems. Anterior thoracolumbar plates and screws or pedicle screw and rod systems are among the options for the surgeon to use.

The use of allograft and/or autograft with the SupStance VBR System is optional.

#### **Statement of Technological Comparison**

The subject device shares the same intended use, basic design concepts, and materials as that of the predicate devices. Performance testing included the types of mechanical testing recommended for vertebral body replacement systems (static and dynamic compression testing, static and dynamic torsion testing, and expulsion testing) in the "FDA Guidance for Industry and FDA Staff, Spinal System 510(k)s" (issued May 3, 2004). The data collected confirms that the mechanical properties of the proposed line extension to the SupStance VBR System product line are comparable to those of the predicate devices. The information and data collected support a claim of substantial equivalence for the proposed SupStance VBR System, Line Extension to the specified predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

PTIB Xavier Arnozan  
% Mr. Marc Bernard  
Regulatory Affairs Director  
Avenue du Haut-Lévêque  
33600 Pessac-France

JUN 30 2008

Re: K081564  
Trade/Device Name: Creaspine SupStance Vertebral Body Replacement System  
Regulation Number: 21 CFR 888.3060  
Regulation Names: Spinal intervertebral body fixation orthosis  
Regulatory Class: II  
Product Code: MQP  
Dated: June 3, 2008  
Received: June 4, 2008

Dear Mr. Bernard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K081564

Device Name: Creaspine SupStance Vertebral Body Replacement System,  
Line Extension

### Indications for Use:

The Creaspine SupStance Vertebral Body Replacement System, Line Extension, (SupStance VBR System) is a vertebral body replacement system intended to replace a vertebral body. The SupStance VBR System is designed for use in the thoraco-lumbar spine (T1- L5) to replace a collapsed, damaged, or unstable vertebral body during tumor or trauma (i.e., fracture) management procedures. The SupStance VBR System is intended to be used with supplemental internal fixation systems. Anterior thoracolumbar plates and screws or pedicle screw and rod systems are among the options for the surgeon to use.

The use of allograft and/or autograft with the SupStance VBR System is optional.


Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K081564

Page 1 of 1